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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,085	03/02/2007	Bernard Verrier	033339/305755	9648

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,085	VERRIER ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 and 4-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 4-9* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 1/17/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments filed 1/17/2008, with respect to the rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite have been fully considered but they are not persuasive.

Claims 2 and 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim amendments clarify most of the issues previously identified. However, the term "n-alkanol", short for normal-alkanol (i.e., an n- or normal-alcohol) is understood to refer only to compounds with an OH group attached to a terminal C, more precisely named as a 1-alcohol. The inclusion of both 1-alcohols and 2-alcohols render the claims indefinite, as 2-alcohols do not fall within the definition of n-alcohols. Thus, compounds which fall within the metes and bounds of the claims is still unclear.

In addition, the rejection presented below has been made based on the new claim language of new independent claim 9.

3. Applicant's arguments filed 1/17/2008 with respect to the rejection of claims 1-2, 4-6 and 8 under 35 U.S.C. 102 (a) as being anticipated by Marcet et al. (British Journal of Pharmacology; 2004; 141, 905-914) have been fully considered but they are not persuasive.

Claims 2 and 4-6 and 8-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Marcet et al. (British Journal of Pharmacology; 2004; 141, 905-914)

Applicant has provided a certified translation of the French priority document, FR 0308064, filed 7/2/2003. However, this document fails to provide written support for the newly introduced independent claim 9. Specifically, none of the following are disclosed: 1) a method for "partially or fully" activating CFTR channels; 2) a genus of "a mammal in need of such treatment" (activation of CFTR channels), although some pathological conditions have been disclosed, including cystic fibrosis, "atypical cystic fibrosis", obstructions of the bronchial tract, obstructions of the digestive (pancreatic or intestinal) tracts, cardiovascular diseases and kidney diseases; 3) "mixtures" of linear C_6-C_{10} n-alkanols; or 4) administration of an n-alkanol "in an amount sufficient to generate in the vicinity of said cell membranes a concentration of said n-alknaol sufficient to partially or fully open said CFTR in said cell membranes". Therefore, the instant claims are still accorded the filing date of the international application date, 6/29/2004; the reference is still applicable as a 102(a) reference.

The rejection is maintained for the reasons of record.

Claim Objections

4. Claim 9 is objected to because of the following informalities: the reference to C^6-C_{10} appears to be a typographical error of a 6 superscript, where the intended reference is to C_6-C_{10}, where the 6 should be a subscript, referring to the number of C atoms in the linear n-alkanols claimed. Appropriate correction is required.

5. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 2 recites alcohols that have the OH group in the 2-position, compounds that do not fall into the group recited in the independent claim 9 of a "linear n-alkanol". Claim 2 expands, rather than narrows the subject matter of the compounds of claim 9.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2 and 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly introduced claim 9 (now the independent claim on which all other claims depend) recites administration of at least one linear n-alkanol to "a mammal in need of such treatment" (activation of CFTR channels). It is not clear which mammals fall within the metes and bounds of this phrase; the first consideration that is unclear is which

disease condition is required for inclusion into the group of mammals recited: whether only individuals with one of the disease conditions recited in claim 4 are included; or whether mammals are also included that are heterozygous for the CF gene, mammals that are generally healthy, but may be more susceptible to pathologies such as asthma, nasal polyposis, etc., as outlined in the specification (e.g., p. 5, lines 20-p. 6, line 10); and/or whether mammals with general cardiovascular diseases and kidney diseases are also included (see specification, p. 8, lines 34-35), a disease state that may or may not be related to a dysfunctional CFTR channel. Secondly, it is also not clear whether all patients with cystic fibrosis would be included, or just those that have some demonstrated genetic or functional CFTR channel defect fall within the scope of "a mammal in need of such treatment".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2, 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly introduced independent claim 9 does not have written support in the application as filed, and therefore comprises new matter. Applicant has pointed to locations "throughout the current application", in particular in the abstract, and p. 3,

paragraphs 30-31 of the published application in support of claim 9. However, none of these locations disclose: 1) a method for "partially or fully" activating CFTR channels; 2) a genus of "a mammal in need of such treatment" (activation of CFTR channels), although some pathological conditions have been disclosed, including cystic fibrosis, "atypical cystic fibrosis", obstructions of the bronchial tract, obstructions of the digestive (pancreatic or intestinal) tracts, cardiovascular diseases and kidney diseases; 3) "mixtures" of linear C_6-C_{10} n-alkanols; or 4) administration of an n-alkanol "in an amount sufficient to generate in the vicinity of said cell membranes a concentration of said n-alknaol sufficient to partially or fully open said CFTR in said cell membranes".

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614